

STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

Important Safety Notice

February 14, 2013

Topic: Illegal Handheld Dental and Veterinary X-Ray Units May Present Hazard

The U.S. Food and Drug Administration (FDA) has posted a warning for dental and veterinary professionals about certain potentially unsafe hand-held dental X-ray units. The X-ray units have been sold under various manufacturer names via the Internet and directly shipped to customers from Southeast Asia.

The FDA, through regulations found in Title 21, Code of Federal Regulations (CFR), requires that X-ray producing machines undergo performance testing to make sure they are safe for use and do not cause unnecessary radiation exposure to both the operator and the patient. All hand-held dental X-ray units that have been certified by the manufacturer to meet the FDA's radiation safety standards bear a certification label/tag, a warning label, and an identification (ID) label/tag on the unit's housing. All labels/tags should be in the English language and permanently affixed or inscribed on each product so that they are legible and readily accessible when the X-ray unit is fully assembled for use.

The CERTIFICATION LABEL should state: "This product complies with 21 CFR 1020.30 - 1020.31," "This product complies with 21 CFR Subchapter J" or other similar language.

The WARNING LABEL must be on the X-ray panel of the unit and state these exact words: "This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

The IDENTIFICATION (ID) LABEL must contain:

- The full name and address of the manufacturer of the unit
- The place of manufacture
- The month and year of manufacture

Some of the X-ray units sold from Southeast Asia directly to customers have not been reviewed by FDA and do not meet FDA radiation safety requirements and are not legal for sale in the United States. The FDA is currently investigating the extent of the problem.

All users of hand-held dental and veterinary X-ray units are asked to verify the presence of required FDA labels described above. You should ask vendors if the device has been reviewed by FDA and has met their requirements before purchasing an X-ray machine on the Internet. You may e-mail the FDA, Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV or call 800-638-2041 or 301-796-7100 for more information.

Should you have any further questions, recommendations or suggestions, please do not hesitate to contact Brian Vamvakias, Supervisor, X-Ray Certification and Mammography Unit at Brian.Vamvakias@state.co.us or (303) 692-3427.

For further information on this event please refer to the following websites:

FDA Notice: <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/AlertsandNotices/ucm291214.htm>

Medical Device Searchable Database:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/ucm2007460.htm#databases>